or person employing the additive under the provisions of this section shall keep and maintain throughout the period of use of the additive and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation. Those records shall be made available upon request at all reasonable hours by any officer or employee acting on behalf of the Secretary of Health and Human Services. Those officers or employees shall be permitted to conduct inventories of raw and finished materials on hand as are deemed necessary to verify the records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive contained therein.

(2) The amounts of additive and each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) When the food additive is added as a nutrient to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and these foods comply with the requirements of part 105 of this chapter, the food additive is exempt from the limitations in paragraphs (c)(1) through (4) and (d) of this section and may be used in those foods at levels not to exceed good manufacturing practices.

[43 FR 27784, June 27, 1978, as amended at 46 FR 59968, Dec. 8, 1981; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.375 Potassium iodide.

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:

(1) The name of the additive.

(2) A statement of the concentration of the additive in any mixture.

§ 172.379 Vitamin D_2.

Vitamin D_2 may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D_2, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. Vitamin D_2 is produced by ultraviolet irradiation of ergosterol isolated from yeast and is purified by crystallization.

(b) Vitamin D_2 meets the specifications of the 2015 Food Chemical Codex, 9th edition (through Third Supplement), effective December 1, 2015, pp. 1260–1261, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) The additive may be used as follows:

Category of Food	Maximum Levels in Food (as Served)
Edible plant-based beverages intended as milk alternatives	84 IU/100 g.
Edible plant-based yogurt alternatives	89 IU/100 g.
Soy beverage products	89 IU/100 g
Soy-based butter substitute spreads	330 IU/100 g
Soy-based cheese substitutes and soy-based cheese substitute products	270 IU/100 g

[74 FR 11022, Mar. 16, 2009, as amended at 78 FR 71463, Nov. 29, 2013; 81 FR 46581, July 18, 2016]

§ 172.380 Vitamin D_3.

Vitamin D_3 may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D_3, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D_3 occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D_3 meets the specifications of ''Vitamin D_3,'', Food Chemicals Codex, 11th ed., copyright 2018, pp. 1243–1244, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) The additive may be used as follows:

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 330 milligrams (mg) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

(3) At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(4) At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(5) At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under § 170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§ 133.165 and 133.183 of this chapter, and those defined by standard of identity in § 133.148 of this chapter.

(6) At levels not to exceed 500 IU per 240 mL (prepared beverage) in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D_3 provided by the product does not exceed 1,000 IU per day.

(7) At levels not to exceed 1.0 IU per kilocalorie in foods represented for use as a sole source of nutrition for enteral feeding.